

3¾ dozen bottles, each containing 6 fluid ounces, of Dr. Sibbett's Improved Big Six; and 1¾ dozen bottles, each containing 6 fluid ounces, of Dr. Sibbett's Original Big Six at Detroit, Mich.; alleging that the articles had been shipped by the Sibbett Medicine Co., Cleveland, Ohio, on or about April 9, 1943; and charging that they were misbranded.

Examination disclosed that the articles were of the same composition, consisting essentially of 227 grains of Epsom salt per fluid ounce, together with small amounts of ammonium chloride, caffeine citrate, tincture of ferric chloride, and oil of lemon in water.

The articles were alleged to be misbranded in that the statements appearing on their labels which represented and suggested that the articles would be effective in relieving colds and headaches; that they contained quinine sulfate and glycerin; and that they contained solution of iron (tincture of iron chloride), citric acid, caffeine citrate, and oil of lemon in amounts sufficient to constitute active ingredients, were false and misleading since the articles would not be effective in relieving colds and headaches, did not contain quinine sulfate and glycerin, and did not contain solution of iron, citric acid, caffeine citrate, and oil of lemon in amounts sufficient to constitute active ingredients. The articles were alleged to be misbranded further (1) in that the words, statements, and information required by the law to appear on the label or labeling were not prominently placed thereon with such conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the required words, statements, and other information were obscured by a red figure 6 covering the main portion of the label, except the firm's name and address; and (2) in that the labeling failed to bear adequate directions for use, since the articles were laxatives and the directions which appeared in the labeling provided for continuous administration, whereas a laxative should not be used continuously.

On July 16, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS³

1106. Adulteration and misbranding of "Be" Bex, and misbranding of Hi-Test Pine Extract. U. S. v. Oxford Products, Inc., and Jerome H. Rose. Pleas of guilty. Fine of \$300 and costs imposed against each defendant; sentence against corporate defendant suspended. (F. D. C. No. 9673. Sample Nos. 6725-F, 8706-F.)

On September 16, 1943, the United States attorney for the Northern District of Ohio filed an information against Oxford Products, Inc., Cleveland, Ohio, and Jerome H. Rose, president of the corporation, alleging shipment from the State of Ohio into the State of Iowa of a quantity of "Be" Bex, on or about December 23, 1942, and from the State of Ohio into the State of Missouri of a quantity of Hi-Test Pine Extract, on or about January 16, 1943.

Analysis of the "Be" Bex disclosed that it contained approximately 330 International Units of vitamin B₁ per fluid ounce. The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, since it was represented to contain 660 International Units of vitamin B₁ per fluid ounce, whereas it contained less than that amount. It was alleged to be misbranded because of false and misleading statements on its label which represented and suggested that the article would aid in promoting the appetite and in protecting the body from nerve disorder resulting from vitamin deficiency; that it would be efficacious in the cure, mitigation, treatment, or prevention of retarded growth, constipation, migraine headaches, and nutritional anemia; and that it would be helpful in the promotion of greater vigor, better functional digestion, and wholesomeness of the skin. It was alleged to be misbranded further in that the statements on its label were misleading which represented and suggested that poor appetite, nerve disorder, retarded growth, constipation, migraine headaches, nutritional anemia, lack of vigor, poor digestion, and unwholesomeness of the skin were usually caused by lack of the vitamins contained in the article; and that the user might reasonably expect correction and alleviation of those conditions by the use of the article, whereas such conditions are not usually caused by lack of the vitamins contained in the article, but usually result from other causes, and the user might not

³ See also No. 1102.

reasonably expect correction and alleviation of those conditions by use of the article as directed or otherwise, since it would not ordinarily be efficacious for such purposes. The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

Analysis of the Hi-Test Pine Extract disclosed that it had the odor of creosote, and contained not more than 1.49 minims of chloroform per fluid ounce and not more than 4.36 percent of alcohol by volume. The article was alleged to be misbranded in that the statements on its label, "22 Minims Chloroform per fld. oz.," and "Alcohol 17% Chloroform 22 Minims Per Fluid Ounce," were false and misleading; and in that the words "Pine Extract" were misleading, since they suggested that the article was composed solely of pine extract and derived its therapeutic properties solely from the pine extract, whereas the article contained therapeutically active ingredients other than pine extract, i. e., creosote and chloroform.

On October 25, 1943, the defendants entered pleas of guilty and the court sentenced the individual defendant to pay a fine of \$50 on each of the first 4 counts relating to the "Be" Bex, and a fine of \$100 on the fifth count relating to the Hi-Test Pine Extract, a total fine of \$300 and costs. The same sentence was imposed against the corporate defendant, but this sentence was suspended.

1107. Adulteration and misbranding of carbon tetrachloride. U. S. v. National Package Drugs, Inc. Plea of guilty. Fine, \$2,000. (F. D. C. No. 9643. Sample Nos. 29264-F, 29277-F, 37441-F.)

On June 19, 1943, the United States attorney for the Eastern District of Missouri filed an information against the National Package Drugs, Inc., St. Louis, Mo., alleging shipment on or about October 15 and December 22, 1942, from the State of Missouri into the States of Virginia and Georgia of quantities of carbon tetrachloride which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which, carbon tetrachloride, was recognized in the United States Pharmacopoeia official at the time of shipment, but its quality or purity fell below the standard set forth in that compendium since, in the case of the Georgia lot, the weight of the residue from the evaporation of 50 cc. exceeded 0.001 gram, the maximum permitted by the Pharmacopoeia, and the amount of the free chlorine and carbonizable substances exceeded the maximum permitted; and, in the case of the Virginia lot, the article was not odorless but had an odor resembling paint, and it contained carbonizable substances in excess of the amount permitted; and the difference in quality and purity from the standard was not stated plainly upon the label.

Both lots were alleged to be misbranded in that the statement, "Carbon Tetrachloride U. S. P.," borne on the label of the article, was false and misleading.

On October 26, 1943, the defendant having entered a plea of guilty, the court imposed a fine of \$500 upon each of 4 counts, a total fine of \$2,000.

1108. Adulteration and misbranding of tincture of nux vomica. U. S. v. Kremers-Urban Co. Plea of nolo contendere. Fine, \$100. (F. D. C. No. 9656. Sample No. 38025-F.)

On June 16, 1943, the United States attorney for the Eastern District of Wisconsin filed an information against the Kremers-Urban Co., a corporation, Milwaukee, Wis., alleging shipment on or about January 14, 1943, from the State of Wisconsin into the State of Illinois of a quantity of the above-named product.

The article was alleged to be adulterated in that it purported to be and was represented as tincture of nux vomica, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth therein since the Pharmacopoeia provides that tincture of nux vomica shall yield from each 100 cc. not more than 0.125 gram of strychnine, whereas the article yielded not less than 0.144 gram of strychnine per 100 cc., and its difference in strength from the standard set forth in the compendium was not plainly stated on the label.

The article was alleged to be misbranded in that the statements, "Tincture Nux Vomica U. S. P. Each 100 cc. contains 0.115 Gm. Strychnine," borne on its label, were false and misleading.

On January 6, 1944, the defendant having entered a plea of nolo contendere, the court imposed a fine of \$50 on each of 2 counts.